EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF MANAGEMENT AND BUDGET

WASHINGTON, D.C. 20503

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OMB

April 4, 1978

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer

Department of Defense
Veterans Administration
Central Intelligence agency
National Science Foundation
Office of Science and Technology Policy
Department of Justice
Department of Energy
National Aeronautics and Space Administration
Environmental Protection Agency
Department of Agriculture

SUBJECT: HEW draft proposed report on S. 2579, a bill "To amend the Public Health Service Act to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes."

The Office of Management and Budget requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

A response to this request for your views is needed no later than noon Thursday, April 6, 1978. (Subcommittee markup of S. 2579 is scheduled for Friday a.m., April 7).

Questions should be referred to John Lively (395-4794 ) or to Jim Stimpson (395-3736 ), the legislative analyst in this office.

Naomi R Sweeney

Naomi R. Sweeney, for
Assistant Director for
Legislative Reference

Enclosures

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The Honorable Harrison A. Williams
Chairman, Committee on Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in response to your request for a report on S. 2579, a bill "To amend the Public Health Service Act to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes."

In summary, the Department agrees with the purposes of the bill and is prepared to recommend that it be enacted, provided that several amendments are made. We do not believe that it is appropriate for public advisory bodies to supervise or monitor programs of any department or agency of the Federal Government. We therefore recommend that all provisions of S. 2579 [particularly section 1802(b)(2)] which authorize the proposed President's Commission to review specific programs and make determinations concerning them should be deleted. Furthermore, the bill would require the President's Commission to separately advise each of some 20 Federal agencies engaged in research involving human subjects. This requirement is inconsistent with recommendations made by the existing National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that "Federal law should be enacted or amended to authorize the Secretary of Health, Education, and Welfare to promulgate regulations governing review of all research involving human subjects that is subject to Federal regulations." The Department believes that S. 2579 should be amended to incorporate the recommendations of the National Commission. Additional suggestions for amendment are mentioned below.

S. 2579 contains the following provisions:

(1) The bill would establish a President's Commission to be composed of eleven members appointed by the President with the advice and consent of the Senate. Five members of the Commission are to be especially qualified by virtue of their experience and background in

biomedical or behavioral research involving human subjects. Six members of the Commission are to be distinguished in the fields of medicine; law; ethics; theology; the biological, behavioral, and social sciences; philosophy; humanities; health administration; government; and public affairs. These members should not be or have been engaged in biomedical research involving human subjects. The Secretary of Defense, the Director of the Central Intelligence Agency, the Director of the Office of Science and Technology Policy, the Administrator of Veterans' Affairs (sic) [the Veterans Administration?], and the Director of the National Science Foundation are to designate nonvoting, ex-officio advisers to the President's Commission.

(2) The President's Commission is to issue a biannual report on the protection of human subjects of biomedical and behavioral research after reviewing the relevant rules, policies, and guidelines of each Federal department and agency. Furthermore, the Commission is authorized to review in detail any program of any department or agency (including the Department of Defense and the Central Intelligence Agency) to determine whether the human subjects of any biomedical or behavioral research involved in such program are adequately protected.

(3) The President's Commission is to complete any unfinished business of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

(4) The President's Commission is to undertake studies of the ethical, social, and legal implications of advances in biomedical and behavioral research and service, including the implications of such advances for individuals and society and for public policy. The Commission is also to analyze the laws and moral and ethical principles governing the use of technology and allocation decisions involved in health care delivery.

(5) The President's Commission is to undertake studies of: informed consent to health care delivery and treatment; defining of death, including the question of developing a uniform definition of death, and of the ethical, moral, social, and legal implications of voluntary testing for genetic diseases and related counseling information and education programs.

(6) The President's Commission is to undertake a study of available mechanisms designed to safeguard the privacy of research subjects and of patient records.

(7) With respect to the mandates listed above, the President's Commission is to be charged with issuing reports to the Congress, Federal departments and agencies, and to the public. When a report and recommendations

are made to a particular department or agency, that department or agency must publish the report in the Federal Register within 60 days and provide opportunity for public comment. Within 180 days of the date of publication in the Federal Register, the department or agency must take appropriate action or publish in the Federal Register a notice that it deems such action inappropriate. Annual reports to the President and appropriate Congressional Committees are required. The reports are to indicate the recommendations made by the President's Commission and the subsequent actions of the affected department or agency.

(8) Other provisions of the bill call for the establishment of ethics advisory boards in each executive or military department to advise each department head with respect to ethical and moral issues. These boards are to coordinate their practices and agenda with the President's Commission.

(9) Finally, the bill includes administrative provisions for the conduct of the President's Commission's business and repeals conflicting provisions of the National Research Act and the Public Health Service Act.

The Department is in full agreement with the intent of S. 2579 to evaluate policies pertaining to human subjects of biomedical and behavioral research, and to evaluate the implications of genetic testing, counseling, and education programs.

We cannot help but question, however, whether a Commission for the protection of human subjects will be qualified to address questions pertaining to analysis of scientific and technological advances, the principles governing the use of technology in medical practice, public attitudes toward such advances, and evaluation of resource allocation decisions.

Certain of these charges, including those relating to the definition of death and the elements of informed consent in the delivery of health services, are matters which are being addressed by the courts and legislatures of the several states among those matters reserved to their jurisdiction by the 10th Amendment. It would appear that the opportunity for the President's Commission to make a significant contribution in these areas may be limited. Furthermore, the expertise needed to carry out such studies may be very different from that required to evaluate safeguards of the rights and well-being of human subjects. The stated qualifications for membership on the Commission do not seem to be well suited to these responsibilities.

Similarly, the Department agrees with the intent of S. 2579 to develop a uniform policy throughout the Federal Government for the protection of human research subjects. On the basis of its earlier efforts involving eleven Federal agencies to develop such a policy, the Department can attest to the general recognition and acceptance within the executive branch of a need for such a mechanism. The Department's efforts to this end were halted because section 202 of P.L. 93-348, the National Research Act, required the National Commission for the Protection of Human Subjects to study how a uniform Federal policy could best be accomplished. The National Commission recently completed its study of this matter and has recommended that HEW take the lead in developing such a policy. Initial steps to implement the recommendations of the Commission have already been taken. As currently drafted, S. 2579 proposes a much more diffuse approach than that expressed in the National Commission's recommendations. Where the National Commission recommends establishment of a single focus within the executive branch, the present bill, S. 2579, would require that the President's Commission make separate recommendations to some 20 different departments and agencies, and imposes a timetable for response which would inhibit, if not actually prevent, interagency coordination. We agree with the National Commission that reasonable regulation in this area requires the designation of a responsible lead agency. Sound administrative practice also requires that the lead agency seek the advice and counsel of other components of the Federal Government facing similar problems. Historically, the principal responsibility has rested with the Department of Health, Education, and Welfare. We believe that S. 2579 could be modified in such a way that the proposed President's Commission could work together with the Department in carrying out the recommendation of the National Commission.

Additionally, S. 2579 charges the President's Commission to restudy matters of patient and research subject privacy already extensively considered by the Privacy Protection Study Commission. The report of the Privacy Protection Study Commission has been widely acclaimed, and its recommendations are already the subject of several legislative proposals before the Congress. The privacy studies in S. 2579 appear, therefore, to be redundant and unnecessary.

Finally, the list of departments and agencies entitled to designate ex-officio advisory members is not representative of those currently supporting health-related research. Specifically, the Department of Energy (9.7%), the National Aeronautics and Space Administration (2.3%), the Environmental Protection Agency (2.0%), and the Department of Agriculture (1.7 %) are excluded, while the National Science Foundation (1.0%) and the intelligence community which supports a vanishingly

small portion of such research areincluded. The Department of Health, Education, and Welfare is limited to one representative, even though it supports about 40% of such research and regulates through the Food and Drug Administration an additional 25%.

We therefore recommend that before S. 2579 is favorably considered that changes reflecting the concerns mentioned above be made in the bill. Furthermore, we believe that the National Commission for the Protection of Human Subjects should be permitted to complete its studies, many of which bear on the issues addressed by S. 2579, before final amendment of the bill is undertaken.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Joseph A. Califano, Jr.

NIH/OD/DLA:CMcCarthy:hh, 496-3471
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